

# **EXHIBIT A**

**MESSA & ASSOCIATES, P.C.**

**By: Joseph L. Messa, Jr., Esquire  
Irene M. McLafferty, Esquire  
Thomas N. Sweeney, Esquire  
Attorney I.D. Nos.: 53645/60120/84192  
123 South 22nd Street  
Philadelphia, Pennsylvania 19103  
(215) 568-3500 / Fax: (215) 568-3501**

**This is not an Arbitration Matter.  
Assessment of Damages Hearing  
is Required.  
Major Jury.**



**Attorney for Plaintiffs**

**DANIEL MOORE, as the Administrator :  
of the Estate of RIVER D. MOORE, a :  
minor, Deceased, and DANIEL MOORE :  
and KATY MOORE, h/w, Individually :  
in their own right, :**

**COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY  
December Term, 2011  
No.**

**v.**

**JOHNSON & JOHNSON, et al.**

**CIVIL ACTION - PRODUCTS LIABILITY  
NOTICE TO PLEAD**

**NOTICE**

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Lawyer Referral Service  
Philadelphia Bar Association  
1101 Market Street, 11<sup>th</sup> Floor  
Philadelphia, PA 19107  
(215) 238-6338

**ADVISO**

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) días de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte pueda decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ESTA OFICINA LO PUEDE PROPORCIONAR CON INFORMACION ACERCA DE EMPLEAR A UN ABOGADO. SI USTED NO PUEDE PROPORCIONAR PARA EMPLEAR UN ABOGADO, ESTA OFICINA PUEDE SER CAPAZ DE PROPORCIONARLO CON INFORMACION ACERCA DE LAS AGENCIAS QUE PUEDEN OFRECER LOS SERVICIOS LEGALES A PERSONAS ELEGIBLES EN UN HONORARIO REDUCIDO NINGUN HONORARIO.

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**DANIEL MOORE, as the Administrator :  
of the Estate of RIVER D. MOORE, a :  
minor, Deceased, and DANIEL MOORE :  
and KATY MOORE, h/w, Individually :  
in their own right, :  
2172 Fairview Road :  
Ellensburg, WA 98926, :**

**Plaintiff, :**

**v. :**

**JOHNSON & JOHNSON :  
One Johnson & Johnson Plaza :  
New Brunswick, N.J. 08933-0001 :  
and :  
MCNEIL-PPC, INC. :  
7050 Camp Hill Road, :  
Fort Washington, PA 19034-2210 :  
and :  
MCNEIL CONSUMER HEALTHCARE :  
7050 Camp Hill Road, :  
Fort Washington, PA 19034-2210 :  
and :  
MCNEIL CONSUMER & SPECIALTY :  
PHARMACEUTICALS, a division of :  
McNeil PPC, Inc. :  
7050 Camp Hill Road, :  
Fort Washington, PA 19034-2210 :  
and :**

**COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY**

**December Term, 2011**

**No.**

**COSTCO WHOLESALE** :  
**CORPORATION** :  
**999 Lake Drive,** :  
**Issaquah, WA 98027** :  
**and** :  
**WILLIAM C. WELDON** :  
**515 Waterview Place** :  
**New Hope, PA 18938-2257** :  
**and** :  
**COLLEEN GOGGINS** :  
**7 Constitution Hill E** :  
**Princeton, NJ 08540-6739** :  
**and** :  
**ROSEMARY CRANE** :  
**33 Teal Drive,** :  
**Langhorne, Pennsylvania 19047** :  
**and** :  
**PETER B. LUTHER** :  
**27 Random Rd** :  
**Princeton, NJ 08540-4065** :  
**and** :  
**SUSAN L. LINDQUIST, PH.D.** :  
**85 Hilltop Rd.,** :  
**Chestnut Hill, MA 02467-1806** :  
**and** :  
**MARY SUE COLEMAN, PH.D.** :  
**1150 Beal Avenue** :  
**Ann Arbor, MI 48109-2113** :  
**and** :  
**DAVID SATCHER, M.D., Ph.D.** :  
**720 Westview Drive SW** :  
**Atlanta, GA 30310-1495** :  
**and** :  
**MICHAEL M.E. JOHNS, M.D.** :  
**1440 Clifton Road** :  
**Atlanta, GA 30322** :  
**and** :  
**INMAR, INC.,** :

2601 Pilgrim Court,	:
Winston-Salem, N.C. 27106	:
and	:
CAROLINA SUPPLY CHAIN	:
SERVICES, LLC	:
2601 Pilgrim Court,	:
Winston-Salem, N.C. 27106	:
and	:
CAROLINA LOGISTICS SERVICES,	:
LLC,	:
2601 Pilgrim Court,	:
Winston-Salem, N.C. 27106	:
and	:
WIS INTERNATIONAL	:
9265 Sky Park Court, Suite 100,	:
San Diego, CA 19123,	:
	:
Defendants.	:
_____	:

**VERIFIED COMPLAINT**

Plaintiffs Daniel Moore, as the Administrator of the Estate of River D. Moore, a minor, deceased, and Daniel Moore and Katy Moore, h/w, individually and in their own right, by and through their undersigned counsel, bring this Complaint against the Defendants set forth above and in support thereof aver as follows:

**I. INTRODUCTION**

1. This is a tragic case in which Plaintiffs Daniel and Katy Moore seek compensatory and punitive damages from Defendants Johnson & Johnson, its executives and subsidiary companies, for their willful and reckless conduct which needlessly caused the death of two year-old River Moore simply to preserve the continuation of their billion dollar revenue

stream of pediatric medicines, including Children's Tylenol and, for the executives themselves, to protect their corporate careers.

2. Defendant Johnson & Johnson, a Fortune 50 Company with \$60 billion in annual sales, knew of defects, impurities and contamination in their children's drugs and, yet, embarked on a "phantom" or "stealth" recall of these drugs to hide these problems so the general public, ignorant of the dangers, would continue buying and administering these brand name drugs to their children.

3. Once Johnson & Johnson learned of the manufacturing defects in its pediatric medicines, it willfully and consciously engaged in a widespread scheme to keep the public in the dark.

4. Even after being caught red-handed by federal investigators in trying to hide defects at their plants and in their drugs, Johnson & Johnson, its subsidiaries and executives failed to take adequate steps to protect children, particularly River Moore, from the dangers of their products.

5. Despite knowing that they had sold millions of bottles of their contaminated and defective medicines to the unsuspecting public, Johnson & Johnson and its executives sought to downplay the health risks to parents who were giving these drugs to their children across the United States.

6. On May 27, 2010, Colleen Goggins, the Worldwide Chairman, Consumer Group of Johnson and Johnson sought to downplay the problem before Congress by claiming that "the health risks to consumers from the recalled products were remote" and "McNeil has no indication of a serious adverse medical event caused by any of the issues referenced in the

**recall announcement.**”<sup>1</sup>

7. Months later, Johnson & Johnson’s Chairman of the Board and Chief Executive, William C. Weldon again attempted to minimize the danger posed to children by these over-the-counter medicines and admitted publically that the company calculated that, “I think we had looked at this closely and determined there was **no risk, no safety hazard, no risk to patients who consumed these products.**”<sup>2</sup>

8. Johnson & Johnson, its Chief Executive Weldon and Worldwide Chairman Goggins were wrong.

9. Despite awareness of widespread problems with all of their pediatric medicines, Johnson & Johnson and their executives did not immediately withdraw all of those children’s drugs from the market, instead perpetuated the danger to the public through their public pronouncements and piecemeal recalls.

10. Their conscious decision to keep contaminated drugs on the market and their public minimization of the dangers killed two-year old River Moore.

11. On July 22, 2010, Katy Moore gave her healthy son River Children’s Tylenol to treat a fever.

12. At the time, Katy Moore did not know, and had no way of knowing, that the medicine administered to her son was contaminated, impure, defective and would kill him.

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<sup>1</sup> Hearing of the House Committee on Oversight and Governmental Reform, U.S. House of Representatives, *Johnson & Johnson’s Recall of Children’s Tylenol and Other Children’s Medicines and the Phantom Recall of Motrin*, September 30, 2010, Washington, D.C., Testimony of Ms. Colleen A. Goggins, Worldwide Chairman, Consumer Group, Johnson & Johnson, May 27, 2010. (Emphasis added).

<sup>2</sup> Hearing of the House Committee on Oversight and Governmental Reform, U.S. House of Representatives, *Johnson & Johnson’s Recall of Children’s Tylenol and Other Children’s Medicines and the Phantom Recall of Motrin*, September 30, 2010, Washington, D.C. at p. 16. (Emphasis added).

13. But Johnson & Johnson and its highly-compensated executives knew of the problems with their products, and instead intentionally decided to gamble with River Moore's life because they were more concerned with company profits and meeting the Wall Street analysts' earnings projections, than the health and safety of American children.

14. As a result, the contaminated Children's Tylenol, which never should have been on the market in the first place, caused River Moore's liver failure and death.

15. Though it proclaims to being a "credo-based company," boasting that it puts the well-being of its customers first and that Johnson & Johnson's "**first responsibility is to the people that use our products**", Johnson & Johnson's chief executive Weldon admitted, "**I stated and I would state again that we let them (our customers) down. There's absolutely no doubt we let them down. This was not one of our best moments.**"

16. J&J and Weldon's contrition was too late to protect two year-old River Moore who lost his life as a consequence of Johnson & Johnson and its executives' reckless, ill-advised and calculated decisions.

## II. PARTIES

17. Plaintiffs Daniel Moore and Katy Moore, husband and wife, are residents of the State of Washington with an address at 2172 Fairview Road, Ellensburg, WA 98926. They are the natural parents of River Moore. Plaintiff Daniel Moore was appointed Administrator of the Estate of River Moore by the Superior Court of Washington for Kittitas County. A true and correct copy of the Letters of Administration are attached hereto as Exhibit "A."

18. Johnson & Johnson ("J&J") is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson

has more than 250 companies located in 57 countries around the world, including McNeil, and sells consumer products and prescription products throughout Pennsylvania, including in the City and County of Philadelphia and the United States, including its territories. J&J is responsible for McNeil, as well as the manufacture, distribution, marketing and sale of the Children's Tylenol which killed two year-old River Moore.

19. Defendant McNeil-PPC, Inc. (hereinafter "McNeil-PPC") is, upon information and belief, a corporation organized and existing under the laws of the state of New Jersey, and its principal place of business is 7050 Camp Hill Road, Fort Washington, PA 19034-2210. McNeil is the largest consumer company within the Johnson & Johnson Family of Companies. McNeil manufactures, distributes, markets and sells a broad range of well-known brand name, over-the-counter ("OTC") products, including Tylenol®, Motrin®, Zyrtec®, and Benadryl®. Many of McNeil's products are made specifically for children.

20. Defendant McNeil Consumer & Specialty Pharmaceuticals, a division of McNeil PPC, Inc. (hereinafter "McNeil-CSP") is, upon information and belief, a corporation organized under the laws of the state of New Jersey, and its principal place of business is 7050 Camp Hill Road, Fort Washington, PA 19034-2210.

21. Defendant McNeil Consumer Healthcare, a division of McNeil PPC, Inc. (hereinafter "McNeil-CH") is, upon information and belief, a corporation organized under the laws of the state of New Jersey, and its principal place of business is 7050 Camp Hill Road, Fort Washington, PA 19034-2210.

22. Costco Wholesale Corporation ("Costco") is a corporation or other jural entity organized and existing under the laws of the State of Washington. Costco maintains its

headquarters at 999 Lake Drive, Issaquah, WA 98027. Costco operates a retail store at Union Gap, Washington which placed into the stream of commerce the defective and contaminated Children's Tylenol which killed River Moore.

23. William C. Weldon ("Weldon") is an individual and resident of the Commonwealth of Pennsylvania who maintains an address at 515 Waterview Place, New Hope, Pennsylvania. He is the current Chairman and Chief Executive Officer of Johnson & Johnson. Mr. Weldon joined J&J in 1971 and served in several sales, marketing and international management positions. Mr. Weldon was appointed to the Executive Committee and named Worldwide Chairman, Pharmaceuticals Segment in 1998, was elected to the Board of Directors and was named vice Chairman of the Board in 2001. On April 25, 2002, Mr. Weldon became Chairman and CEO of Johnson & Johnson, the position he currently holds. Prior to two year-old River Moore's death, Mr. Weldon had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that allowed contaminated and defective pediatric medicines to be sold to the unsuspecting public. His lack of leadership resulted in the degradation of quality control at J&J, which caused defective medicines to be sold to the public, including the Moores. As described more full herein, on September 30, 2010, Mr. Weldon testified before Congress and admitted responsibility for the acts, omissions, problems at McNeil which ultimately caused two year-old River Moore's death.

24. Colleen Goggins ("Goggins") is an individual and resident of the State of New Jersey and maintains an address at 7 Constitution Hill East, Princeton, N.J. Ms. Goggins was

the Worldwide Chairman of the Johnson & Johnson Consumer Healthcare Segment. In her position, she was a member of the Group Operating Committee (“GOC”) of Johnson & Johnson and reported directly to Mr. Weldon. Prior to River Moore’s death, Ms. Goggins had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that allowed contaminated and defective pediatric medicines to be sold to the unsuspecting public, including the Moores. Her lack of leadership resulted in the degradation of quality control at J&J, which caused defective medicines to be sold to the public. As described more full herein, on September 30, 2010, Ms. Goggins also testified before Congress and admitted responsibility for the acts, omissions, problems at McNeil which ultimately caused two year-old River Moore’s death.

25. Rosemary Crane (“Crane”) is an individual and resident of the Commonwealth of Pennsylvania with an address 33 Teal Drive, Langhorne, Pennsylvania, who, beginning in 2002, was the Company Group Chairman and member of the GOC of Johnson & Johnson with responsibility for McNeil, the McNeil Consumer Healthcare Segment, and the Children’s Tylenol product which killed two year-old River Moore’s death. Ms. Crane had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil’s Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J. As described more fully herein, Ms. Crane was responsible for the acts, omissions, problems at McNeil which ultimately caused two year-old River Moore’s death.

26. Peter Luther (“Luther”) is an individual and, upon information and belief, a resident of the State of New Jersey who maintains a residence at 27 Random Road, Princeton, NJ 08540-4065. Mr. Luther has served as the President of McNeil since January 2009. From 1991 through March 2000, Luther was the franchise director of McNeil’s Consumer & Specialty Pharmaceuticals. From March 2000 through March 2006, Mr. Luther served as President of LifeScan, another J&J subsidiary. From March 2006 through January 2009, Mr. Luther was President of J&J’s North American Beauty Care division. Mr. Luther also has served as a member of the J&J Board of Directors. Throughout the relevant time period, Mr. Luther had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil’s Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J. As described more fully herein, Mr. Luther was responsible for the acts, omissions, problems at McNeil which ultimately caused two year-old River Moore’s death.

27. Susan L. Lindquist, Ph.D. (“Lindquist”) is an individual and, upon information and belief, a resident of the Commonwealth of Massachusetts with an address at 85 Hilltop Rd., Chestnut Hill, MA 02467-1806. Dr. Linquist has served on the Board of Directors since 2004 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time period, Dr. Lindquist had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil’s Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which ultimately caused two year-old River Moore’s death.

28. Mary Sue Coleman, Ph.D. (“Coleman”) is an individual, and upon information and belief, a resident of the State of Michigan with a residence at 1150 Beal Avenue Ann Arbor, MI 48109-2113. Dr. Coleman has served as a member of the Board of Directors at J&J since 2002 and is a member of the Science & Technology Advisory Committee. Dr. Coleman had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil’s Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J. As described more fully herein, Dr. Coleman was responsible for the acts, omissions, problems at McNeil which ultimately caused two year-old River Moore’s death.

29. Michael M.E. Johns, M.D. (“Johns”) is an individual and, upon information and belief, a resident of the State of Georgia and maintains an address at 1440 Clifton Road, Atlanta, Georgia 30322. Dr. Johns has served on the Board of Directors since 2005 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time period, Dr. Johns had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil’s Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

30. David Satcher, M.D., Ph.D. (“Satcher”) is an individual and, upon information and belief, a resident of the State of Georgia and maintains and address at 720 Westview Drive SW Atlanta, GA 30310-1495. Dr. Satcher has served on the Board of Directors since 2002 and is a member of the Science & Technology Advisory Committee. Throughout the relevant time

period, Dr. Satcher had personal knowledge of the deplorable conditions at J&J manufacturing facilities, like those at McNeil's Fort Washington plant, and was integrally involved in and responsible for the decisions that led to the degradation of quality control at J&J, which give rise to the claims at issue in this case.

31. Inmar, Inc., on information and belief, is a North Carolina corporation with a principal place of business located at 2601 Pilgrim Court, Winston-Salem, North Carolina. Inmar, Inc.'s business operations include the processing and management of returned/recalled pharmaceutical products serving retailers, wholesalers, manufacturers and pharmacies. Inmar, Inc. was hired by, and/or acted on behalf of, Johnson & Johnson and/or McNeil to conduct the 2009 Phantom Recall and other "market assessments," including market assessments related to the April 30, 2010 recall. Inmar, Inc.'s involvement in these activities is, in part, the subject of a current Congressional investigation.

32. Carolina Supply Chain Services, LLC, ("CSCS"), on information and belief, is a limited liability company organized under the laws of the State of North Carolina with a principal place of business located at 2601 Pilgrim Court, Winston-Salem, North Carolina. CSCS's business operations include reverse logistics and supply chain management. CSCS's sole member is/was Carolina Logistics Services, LLC. CSCS was/is a subsidiary of Inmar, Inc. CSCS was hired by, and/or acted on behalf of, Johnson & Johnson and/or McNeil to conduct the 2009 Phantom Recall and other "market assessments," including market assessments related to the April 30, 2010 recall. CSCS's involvement in these activities is, in part, the subject of a current Congressional investigation.

33. Carolina Logistics Services, LLC, (“CLS”) is a limited liability company organized under the laws of the State of North Carolina with a principal place of business located at 2601 Pilgrim Court, Winston-Salem, North Carolina. CLS’s business operations include reverse logistics and supply chain management. CLS is the surviving entity of a 2008 merger between CLS and CSCS. CLS’s sole member is Inmar, Inc., and is liable for the acts of CSCS pursuant to the terms of the Articles of Merger, and Article I, Section 3 of the Plan of Merger, between CSCS and CLS dated November 24, 2008, filed December 17, 2008 with the Department of the Secretary of the State of North Carolina, effective December 29, 2008, in accordance with the North Carolina Limited Liability Company Act.

34. WIS International is believed to be a Canadian business entity with its U.S. headquarters located at 9265 Sky Park Court, Suite 100, San Diego, California. WIS International’s business operations include inventory services, compliance audits, price verifications, shopper surveys, discontinued items and product placement allocation. It is believed and therefore averred that WIS International was recruited/hired by Inmar, Inc./CSCS and acted on behalf of Johnson & Johnson and/or McNeil and assisted Inmar, Inc./CSCS, with the conduct of the 2009 Phantom Recall and other “market assessments,” including market assessments related to the April 30, 2010 recall. WIS International’s involvement in these activities is, in part, the subject of a current Congressional investigation.

35. The acts alleged in this Complaint to have been done by Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their

respective business affairs. As detailed at length below, the conduct was specifically authorized by the relevant officers and executive officers of the Defendants.

36. Venue is proper in this Court under Pennsylvania Rules of Civil Procedure 1006 and 2179 because Defendants J&J, McNeil-PPC, McNeil-CSP, McNeil-CH, and Costco regularly and continuously conduct business in Philadelphia County, including the advertising, marketing, distribution and sale of their prescription and non-prescription products to Philadelphia residents and their families through various retail outlets within the limits of the City and County of Philadelphia. Furthermore, upon information and belief, many of the communications, meetings, non-disclosures and tortious conduct which form the basis of the Food & Drug Administration investigation and this Complaint occurred at United States Customs House, Room 900, 2<sup>nd</sup> and Chestnut Streets, Philadelphia, Pennsylvania

### **III. FACTUAL BACKGROUND**

#### **A. Relationship Between Johnson & Johnson and McNeil**

37. Johnson & Johnson, founded in 1886 and is based in New Brunswick, New Jersey, engages in the research and development, manufacture, distribution and sales of various products in the healthcare field worldwide.

38. J&J is comprised of approximately 250 worldwide “operating companies.”

39. These operating companies are organized into business segments, including Consumer Health Care, Medical Devices and Diagnostics, Pharmaceuticals.

40. The Pharmaceutical segment offers products in various therapeutic areas such as anti-infective, antipsychotic, cardiovascular, contraceptive, dermatology, gastrointestinal,

immunology, neurology, oncology, urology, and virology.

41. The Consumer Health Care segment provides products including over-the-counter pharmaceutical products, including the Children's Tylenol.

42. McNeil is an operating company within the Consumer Health Care Segment of Johnson & Johnson, and a member of the Johnson & Johnson corporate partner group.

43. Individual Defendants Weldon, Goggins, Crane, Luther, Satcher, Johns, Coleman and Lindquist all had responsibility for the Consumer Health Care Segment.

44. McNeil is the largest consumer company within J&J.

45. In 1959, J&J acquired McNeil Laboratories, a company focused on direct marketing of prescription products to hospitals, pharmacists and doctors.

46. In 1955, McNeil introduced an acetaminophen based product, Tylenol.

47. A year after acquiring McNeil Laboratories, J&J's McNeil division began selling Tylenol without a prescription.

48. In 1961 McNeil laboratories moved to its Fort Washington, Pennsylvania headquarters.

49. In 1977, McNeil Laboratories created two companies: McNeil Pharmaceutical and McNeil Consumer Healthcare.

50. McNeil Pharmaceutical focused on the marketing of prescription drug products.

51. McNeil-CH focuses on the manufacture and marketing of a variety of over-the-counter (OTC) products for the U.S. market, including Children's Tylenol.

52. These products, including Children's Tylenol, are produced at four separate

McNeil manufacturing facilities located in the United States, Puerto Rico and Canada, including McNeil's Fort Washington and Lancaster, Pennsylvania manufacturing plants.

**B. J&J's "Credo," Principles of Corporate Governance and Policy on Business Conduct**

53. In 1943, Robert Wood, J&J's Chairman from 1932 to 1963, crafted a document entitled "Our Credo" which J&J claims to drive decision making at the company.

54. J&J specifically states that "'Our Credo' is more than just a moral compass. We believe it's a recipe for business success."

55. J&J allegedly believes that "our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality."

56. J&J's "Credo" purportedly dictates that "[w]e must provide competent management, and their actions must be just and ethical" and that "[w]e are responsible to the communities in which we live and work and to the world community as well."

57. According to J&J's Principles of Corporate Governance, corporate governance is also governed by the values set forth in "Our Credo," and that "good corporate governance results from sound processes that ensure that our directors are well supported by accurate and timely information, sufficient time and resources and unrestricted access to management."

58. The Principles of Corporate Governance provide that the responsibilities of the Board of Directors include the duties to "select, oversee and monitor the performance of the senior management team," and to "exercise their business judgment on matter of critical and

long-term significance to the Company in furtherance of what they reasonably believe to be in the best interest of the Company.”

59. J&J’s Policy on Business Conduct emphasizes the Company’s purported dedication to enforcement and compliance with high ethical standards and legal regulations, providing in pertinent part that:

All managers shall be responsible for the enforcement of and compliance with this Policy on Business Conduct including necessary distribution to ensure employee knowledge and compliance. The board of directors or other governing body of each affiliate company shall formally adopt this Policy as its own corporate policy binding on all directors, officers, and employees of the company.

Consistent with our Credo and business philosophy, it is the policy of Johnson & Johnson to comply with the laws of each country in which our companies do business. It is the responsibility of each company’s management and employees to be familiar with the laws and regulations that relate to their business responsibilities and to comply with them.

No aspect of our business is more subject to governmental regulation than the development, manufacture, approval, sales and marketing of our health care products. Because of the complex nature of many of these regulations management must take particular care to ensure appropriate employees are aware of regulatory requirements and take necessary steps to comply with them.

60. J&J has adopted a Code of Business Conduct & Ethics for the members of the Board of Directors and the Executive Offices of the Company.

61. The Code of Business Conduct & Ethics also emphasizes the Board’s responsibilities in ensuring that the Company adheres to ethical and legal regulations and J&J’s policies, providing in pertinent part that:

Each Director and Executive Officer shall be responsible for complying with this Code. Executive Officers of the Company must comply with the Johnson & Johnson Policy on Business Conduct also.

If any Director or Executive Officer believes that a prohibited act under this Code

has occurred, then he or she shall promptly report such belief to the Chairman of the Board, the Presiding Director and the General Counsel. While this is the preferred reporting procedure, and Director or Executive Officer should feel free to report any such alleged prohibited act hereunder to the Chairman of the Audit Committee or the Chairman of the Nominating and Corporate Governance Committee.

Consistent with our Credo and business philosophy, it is the policy of Johnson & Johnson to comply with the laws of each country in which our companies do business. Each Director and Executive Officer shall comply with all applicable laws, rules and regulations, and shall use all reasonable efforts to oversee compliance by employees, other Directors and other Executive Officers with all applicable laws, rules and regulations.

62. J&J and its executives have hidden behind the “Credo” to justify and excuse the widespread unethical and unlawful misconduct as evidenced recently by the sale of defective and contaminated pediatric medicines, including Children’s Tylenol, as well as the Omnicare nursing home kickback scheme, the DePuy kickback scheme and Risperdal scandal.

**C. Lack of Quality Control at Johnson & Johnson**

63. Beginning in approximately 2002, J&J and McNeil sought to cut costs in the quality control department to increase the company’s earnings per share.

64. To accomplish these cost savings, J&J fired experienced quality control staff and replaced them with inexperienced contract workers.

65. The replacement of career quality control staff with contract workers severely weakened the quality control department.

66. The quality control team that tested McNeil’s production lines was so weak, McNeil employees dubbed it the “EZ Pass system.”

67. In 2004, the FDA issued a report citing multiple quality control infractions at

McNeil plants including bad sampling practices, poor record keeping, and incomplete investigations.

68. Despite the FDA's report, quality control issues remained prevalent at McNeil.

69. For example, in 2005, McNeil quality control employees blocked a batch of one million bottles of St. Joseph aspirin from shipment because a sample was found to have a dissolution problem.

70. McNeil quality control management insisted that the batch be passed by ordering that the batch be retested, with the scores of the two tests averaged.

71. This action clearly violated FDA standards and undermined the quality control process.

72. In 2007, McNeil issued an internal memo which cited a high percentage of operator errors in every work center, as well as quality control teams who put little effort into their processes.

73. According to four former J&J employees, prior to 2007, Defendant Weldon drastically cut the J&J corporate compliance group that oversaw all of the different companies and conducted biannual audits of J&J's operating companies.

74. This corporate compliance group implemented "management action plans" for improving quality control.

75. One former J&J executive described the oversight within the company, "[t]he whole idea was creating a Hawthorne effect: If people know they're being watched, they'll do better."

76. After the corporate compliance group was cut at the direction of Defendant Weldon, there was less focus on quality, including in pediatric medicines.

77. One former executive stated, “The heads of the operating companies let their hair down.”

78. In February of 2008, following an FDA inspection of McNeil’s Fort Washington, Pennsylvania plant, the FDA issued another report criticizing McNeil for conducting inadequate investigations.

79. In June of 2009, the FDA issued yet another report regarding the Fort Washington facility citing mishandling of complaints and investigations.

80. Mr. Weldon has stated publicly that, in the wake of the many product recalls at J&J, he created a new position: an operations chief to oversee quality across J&J and report directly to him.

81. Weldon also said the company had been inspecting facilities at all of its 250 operating companies at the time of the 2010 recalls, sought to downplay the problems at the company he runs by stating, “This is not a systemic problem at J&J.”

82. A week after Weldon proclaimed the situation at McNeil to be an anomaly, Johnson & Johnson issued two more recalls one was for Vision Care contact lenses, and the other involved DePuy hip implants.

**D. J&J and McNeil Product Recalls**

83. J&J’s quality control problems has resulted in a significant number of recalls, including the recall of Children’s Tylenol which killed River Moore.

84. This recent string of product recalls is astonishing given the sheer number of recalls over a compressed timeframe involving similar malfeasance and misfeasance by J&J, McNeil and their executives.

**1. The “Phantom” and “Stealth” Recalls of Motrin in July 2009**

85. In August of 2008, McNeil distributed over 88,000 packages of defective Motrin IB 200.

86. McNeil subsequently discovered three months later that there was a dissolution problem with the drug rendering the product ineffective.

87. Rather than publically recall the defective drug, J&J and McNeil hired third-party contractors to perform a clandestine phantom/stealth recall to remove the company’s defective products from retail outlets.

88. This clandestine phantom/stealth recall was done without notification to the customers or the retailers to avoid the public shame, the financial impact and regulatory ramifications of a formal recall.

89. The purpose of the phantom/stealth recall is evidenced in an internal e-mail in which a McNeil executive said, “We are just trying to prevent a recall and a lot of expended dollars.”

90. In another e-mail, a McNeil executive described the success of the phantom/stealth recall by saying, “This was a major win for us as it limits the press that will be seen.”

91. On May 27, 2009, Defendant Peter Luther sent an e-mail approving the unethical

phantom/stealth recall and instructed, "Let's make this happen ASAP."

92. Defendant Luther, who Defendant Weldon praised as being a loyal J&J employee, was not fired for his intimate roll in the phantom/stealth recall.

93. At the direction of J&J and McNeil's third-party contractors, including Inmar, Inc., WIS International, and CSCS, visited various retail outlets and purchased all of the Motrin IB in the store, acting like regular customers.

94. J&J and McNeil directed their third-party contractors, including Inmar, Inc., WIS International, and CSCS, not to discuss their purchases as being a recall of the product.

95. Indeed, J&J's specific instructions to the contractors hired to perform the phantom recall indicated that they were to "quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave ... THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!"

96. J&J and McNeil subsequently misrepresented to the FDA that their third-party contractors were merely performing an audit of retailers to determine whether McNeil should initiate a formal recall.

97. The FDA eventually became aware of the phantom/stealth recall when it received a copy of an internal memo containing the above instructions and confronted McNeil regarding those activities.

98. On July 9, 2009, as a result of the above, McNeil publically recalled the Motrin IB, at a delay of approximately 8 months.

99. This phantom/stealth recall, in part, spurred the House Committee on Oversight

and Government Reform to conduct a Congressional investigation and hold two separate Congressional hearings in 2010.

**2. The September 2009 Recall**

100. In May and June of 2009, the FDA discovered that from April through June 2008, McNeil had used microcrystalline cellulose, an ingredient used in liquid adult and children's Tylenol products, that had been potentially contaminated with a gram negative bacteria, *Burkholder cepacia*.

101. *B. cepacia* infections can be potentially severe, particularly in high-risk patients, such as those with underlying pulmonary disease, cystic fibrosis or compromised immune systems.

102. In July of 2009, instead of simply recalling the defective product, J&J and McNeil once again utilized the services of Inmar to conduct a market assessment to determine how much product remained on store shelves.

103. McNeil's use of partial lots of the contaminated microcrystalline cellulose was determined by the FDA to be a violation of the cGMP regulations.

104. In August/September of 2009, J&J and McNeil initiated a formal recall of nearly 8 million bottles of product.

105. Significantly, this recall did not include all Infant and Children's Tylenol products.

106. September 18, 2009, J&J and McNeil issued a letter to health-care professionals explaining the recall of over-the-counter children's and infant's Tylenol which mentions the

presence of B. cepacia and that children with underlying pulmonary disease, cystic fibrosis or compromising immune systems were at high risk.

107. On September 24, 2009, just six days later, J&J and McNeil described the recall of Children's and Infant's Tylenol on Tylenol.com but contained no mention of B. cepacia, nor did it mention of any conditions that would place a child at high risk.

108. Oddly, J&J and McNeil provided more information about the dangers of their pediatric over-the-counter drugs to physicians than to parents who could purchase these medicines and give them to their children without seeing a doctor.

109. J&J and McNeil intentionally limited the September 2009 recall to only a few lots of Children's and Infant's Tylenol so they could continue selling other suspect and contaminated lots of these over-the-counter pediatric medicines.

110. J&J and McNeil also sought to minimize the dangers to the pediatric population by hiding the known hazards from their public pronouncements.

### **3. The November and December 2009 Recalls**

111. Beginning in the fall of 2008, McNeil began receiving reports regarding musty, moldy odors emanating from McNeil Tylenol pills manufactured at its Las Piedrad, Puerto Rico facility.

112. Despite being obligated to notify the FDA of such reports within three days, McNeil did not fully investigate these reports for approximately one year.

113. Only after the FDA insisted that McNeil conduct a thorough investigation was it discovered that the odor was the result of contamination by a product called 2,4,6-

Tribromoanisole (“TBA”), a pesticide used on the wooden pallets that stored and transported packaging materials for the medications.

114. According to McNeil’s press release, the health effects of TBA have not been well studied.

115. McNeil’s initial recall identified only 5 lots of product for recall.

116. However, in December 2009, J&J and McNeil expanded this recall to include all lots of the Tylenol pills.

117. These recalls were eventually expanded in January, June and July of 2010.

#### **4. The January 2010 Recall**

118. On January 15, 2010, J&J and McNeil expanded their November and December 2009 recalls to encompass additional McNeil products, including Benadryl, Motrin, Roloids, Simply Sleep, St. Joseph Aspirin, and Tylenol, because of the same musty, moldy smell identified in the November and December recall.

119. J&J and McNeil determined that the odor was again caused by the presence of 2,4,6- tribromoanisole (TBA), the same chemical contamination that precipitated the November and December recalls.

#### **5. The April 2010 Recall Of Infant and Children’s Products**

120. In April of 2010, J&J and McNeil recalled approximately 40 types of children’s and infants’ products manufactured at its notorious Fort Washington, Pennsylvania plant because of filth and contamination, including acetaminophen, cellulose, nickel and chromium particulate contamination, involving McNeil’s liquid infant and children’s products including Tylenol,

Motrin, Benadryl, Zyrtec and Tylenol Infants' Drops.

121. In addition to the particulate contamination, some of the products were found to have higher than expected dosage concentrations of the active ingredient, in effect, super-doses of the Tylenol based children's product.

122. J&J and McNeil recalled over 136 million bottles of product, the largest recall of children and infant medicine in history, and shut down manufacturing operations at its Fort Washington plant.

123. Just days after J&J and McNeil's decision to shut down the Fort Washington facility, FDA inspectors, performing an expedited inspection of the facility because of McNeil's past problems, identified some 20 major cGMP violations.

124. As a result of this recall, the House Committee on Oversight and Government Reform conducted an investigation into J&J and McNeil's malfeasance.

125. The House Committee on Oversight and Government Reform held two separate hearings regarding this specific recall, as well as phantom/stealth recall of 2009.

#### **6. The June 2010 Recall**

126. On June 15, 2010, McNeil expanded its January 15, 2010 recall regarding TBA contamination to include five more lots of Benadryl and Tylenol that were allegedly "inadvertently" omitted from the initial recall action.

127. These additional lots were recalled for the same moldy, musty odor that caused the January 2010 recall, contamination by TBA.

#### **7. The July 2010 Recall**

128. On July 8, 2010, McNeil issued yet another recall related to the moldy, musty odor of the January 15, 2010 recall. This time, twenty-one lots of certain Benadryl, Tylenol Meltaways, Motrin, and Tylenol were recalled.

129. These additional lots were recalled for the same moldy, musty odor that caused the January 2010 recall, contamination by TBA.

#### **8. The August 2010 Recall**

130. Between June 22 and July 9, 2010, the FDA conducted an inspection of J&J's Lancaster, Pennsylvania manufacturing plant.

131. The plant is owned by Johnson & Johnson-Merck Consumer Pharmaceuticals (a joint venture between J&J and Merck) but is operated by J&J's McNeil division.

132. On July 9, 2010, the FDA issued a "Form 483" citing problems and deficiencies regarding manufacturing practices at the plant including, but not limited to, unexplained manufacturing discrepancies, improper documentation regarding equipment malfunctions, failure to test medicine batches for quality following an equipment failure, inadequate maintenance records, unlabeled test tubes filled with product sitting on open counters, improper cleansing of utensils used in the drug making process, failure to follow up on consumer complaints, including instances of improper packaging, product type and strength packaging mix-ups, as well as complaints of product "lack of effect."

133. The FDA report cites multiple violations of cGMP regulations at the Lancaster plant, at least five of which were also observed by the FDA at McNeil's Fort Washington facility.

134. On approximately August 10, 2010, Johnson & Johnson-Merck Consumer Pharmaceuticals initiated a recall of one lot of Pepcid Complete Acid Reducer and one lot of Original Strength Pepcid AC because of potential punctures to the bottles during the packaging process.

135. These Pepcid products have disappeared altogether from store shelves.

**9. The October 2010 Recall**

136. On October 18, 2010, McNeil recalled Tylenol 8 Hour caplets related to moldy, musty odors.

137. This recall included Tylenol products manufactured at McNeil's Fort Washington, Pennsylvania plant in March of 2010.

138. The odors were again traced to contamination respecting TBA.

139. One hundred twenty eight thousand bottles of Tylenol were recalled.

**10. The November 2010 Recall**

140. On November 15, 2010, McNeil recalled all Benadryl tablets and junior strength Motrin caplets because of "insufficiencies in the development in the manufacturing process," as well as Roloids Extra Strength Softchews for "uncharacteristic consistence or texture" related to crystallized sugar.

141. On November 24, 2010, McNeil recalled Tylenol multi-symptom liquid products because the packaging did not disclose alcohol as an active ingredient as well as 71,000 packages of Roloids because of an "uncharacteristic consistency or texture" linked to improper sugar crystallization.

**11. The December 2010 Recall**

142. On December 2, 2010, McNeil recalled 12 million bottles of Mylanta and 85,000 bottles of Alterna Gelliquid antacid because the presence of alcohol as an active ingredient in the product that was not disclosed on the packaging.

143. On December 9, 2010, McNeil recalled 13 million packages of Rolaid Extra Strength Plus Gas Softchews and Rolaid Multi-Symptom Plus Anti-Gas Softchews because of the presence of metal and wood particles in the products.

**E. FDA Discoveries of Hidden Problems at J&J and McNeil**

144. Recently, the FDA has grown concerned about the quality of JNJ and McNeil's manufacturing processes and regulatory compliance.

145. Between January 2008 and April 2010, the FDA received 775 reports of adverse events, including 30 deaths, that involving J&J products.

146. After April 30, 2010, the FDA received several hundred more complaints, including seven complaints involving deaths.

147. In January of 2010, the FDA issued McNeil a warning letter expressing the FDA's serious concerns regarding McNeil's control over the quality of its products and the company's failure to aggressively investigate and correct quality problems.

148. On February 19, 2010, the FDA took the extraordinary step of convening a meeting with senior officials from McNeil and J&J, including Defendant Peter Luther, to express the FDA's concern regarding their regulatory violations and pattern of non-compliance.

149. The meeting was held in part to put senior J&J officials on notice regarding the

FDA's concerns about McNeil's corporate culture causing a failure to ensure the purity, potency and safety of its products.

150. In addition, the FDA raised with J&J its concerns about J&J's lack of oversight of McNeil in light of the remarkable string of recalls of McNeil products, the failure to report material information to the FDA in a timely manner, miscalculating and/or misstating risks and benefits of their products, and reactive as opposed to proactive approaches to product quality problems.

151. The problems at McNeil, however, continued including the massive 126 million bottle recall of liquid infant and children's products in April 2010, which directly spurred the 2010 Congressional investigation and hearings.

152. The FDA, in prepared testimony presented at the May 27, 2010 Congressional hearing, noted that "neither upper management at Johnson & Johnson nor at McNeil assured timely investigation and resolution of the issues."

**F. FDA Reports of J&J and McNeil's Lack of Quality Control and Regulatory Compliance**

**1. The April 30, 2010 Report**

153. On or about April 30, 2010, the FDA issued a "Form 483" report (released in early May) pertaining to an inspection of the facilities of McNeil in Fort Washington, Pennsylvania (hereinafter, "the April 30, 2010 Report").

154. The April 30, 2010 Report was issued by the local branch of the FDA, located at the United States Customs House, Room 900, 2<sup>nd</sup> and Chestnut Streets, Philadelphia,



Pennsylvania.

155. The April 30, 2010 Report, authored by four local FDA investigators, and was issued to the Vice President of Operations of McNeil.

156. The April 30, 2010 Report concerned inspections of McNeil which took place between April 19, and April 30, 2010.

157. As detailed in the April 30, 2010 Report, the FDA made 20 separate “observations” about McNeil’s manufacturing deficiencies.

158. These observations included the following:

- a. **Observation 1:** The responsibilities and procedures applicable to the Quality Control Unit are not fully followed. The Quality Control Unit (“QA”) Authorities most responsible for overseeing daily operations at McNeil did not insure that responsibilities for quality assurance were enforced. Such laps in oversight, led to raw materials with “known contaminations” to be included in the manufacture of Subject and Infant's Tylenol drug products which are still on the market today.
- b. **Observation 2:** There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, problems were found with the manufacture of Infant’s Dye-Free Tylenol Suspension Drops, Cherry formula.
- c. **Observation 3:** Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.
- d. **Observation 4:** Control procedures are not established which monitor the output and value the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Specifically, the FDA Report observed that “control procedures used did not validate the manufacturing processes that cause variability in the characteristics of the drug product.” The FDA Report cites the processing of “super potent batches” including batches for Infant's Dye-Free Tylenol Suspension Drops.

- e. **Observation 5:** Written production and process control procedures are not followed in the execution of production and process control functions. Specifically, no Corrective Action Preventative Action (“CAPA”) process was initiated for batches of Subject Products from May 2009 through April 2010 where “foreign material, particulate matter and/or contamination were observed.” In addition, no CAPA was initiated for 46 consumer complaints that were made regarding “foreign materials, black or dark specks from June 2009 to April 2010.”
- f. **Observation 6:** There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed. Specifically, a thorough investigation or additional analytical testing was not conducted for Infant's Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8mL. Further, “vendor lots” from December 4, 2008 and December 23, 2008 were “contaminated with gram-negative organisms.” These lots were used to manufacture the following Tylenol Infant and Subject products which were marketed/distributed and remained within expiration dating as follows:
- (1) Tylenol Infant's Drops, 80 mg/0.8mL, expiration date 11110
  - (2) Tylenol Oral Suspension, expiration date 11110
  - (3) Tylenol Oral Suspension, expiration date 11110
  - (4) Tylenol Oral Suspension, expiration date 11110
  - (5) Subject Tylenol Plus Cold, expiration date 11110
  - (6) Subject Tylenol Plus Multi-Symptom Cold, expiration date 11/10
  - (7) Subject Tylenol Plus Cold, expiration date 11110
  - (8) Subject Tylenol Plus Multi-Symptom Cold, expiration date 12/10
  - (9) Subject Tylenol Oral Suspension, expiration date 11110
  - (10) Subject Tylenol Oral Suspension, expiration 11/10
  - (11) Subject Tylenol Plus Multi-Symptom Cold, expiration date 11110
  - (12) Subject Tylenol Plus Cold & Cough, expiration date 12/10
  - (13) Infant's Tylenol Drops, expiration date 12110
  - (14) Subject Tylenol Oral Suspension, expiration date 12/10
  - (15) Infant's Tylenol Drops, expiration date 12/10
  - (16) Infant's Tylenol Drops, expiration date 12/10
  - (17) Subject Tylenol Oral Suspension, expiration date 11110
  - (18) Subject Tylenol Plus Cold & Cough, expiration date 12/10
  - (19) Subject Tylenol Oral Suspension, expiration date 12/10
  - (20) Subject Tylenol Oral Suspension, expiration date 12/10
  - (21) Subject Tylenol Plus Cold and Cough, expiration date 12/10

- (22) Subject Tylenol Oral Suspension, expiration date 12/10
- (23) Subject Tylenol Oral Suspension, expiration date 12/10
- (24) Subject Tylenol Oral Suspension, expiration date 12/10
- (25) Tylenol Infant's Drops, expiration date 12/10
- (26) Subject Tylenol Plus Cold & Cough, expiration date 12/10.
- g. **Observation 7:** Training is not conducted with sufficient frequency to assure that employees remain familiar with current, good manufacturing practices requirements applicable to them.
- h. **Observation 8:** Procedures describing the handling of all written and all complaints regarding a drug product are not followed. Specifically, a problem in this regard was noted with respect to Infant's Dye-Free Tylenol Suspension Drops, Cherry.
- i. **Observation 9:** Each container dispensed to manufacturing is not examined by a second person to assure weight and measures are correct as stated in the batch records. Specifically, a problem in this regard was noted with respect to Infant's Dye-Free Tylenol Suspension Drops, Cherry.
- j. **Observation 10:** Strict control is not exercised over labeling. Specifically, labeling was accessible to all warehouse operators and personnel and was not kept in a locked environment with limited access.
- k. **Observation 11:** No written testing program designed to assess the stability of drug products. Specifically, there is a lack of stability data to support the expiration date assigned to lots produced following the manufacturing change for Infant's Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8mL.
- l. **Observation 12:** Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products confirm to appropriate standards of identity, strength, quality and purity. Specifically, it is unknown why the firm does not test TSA, a non-selective general microbial growth medium, during growth promotion tests.
- m. **Observation 13:** The quality control unit does not have access to adequate lab facilities for testing and approval or rejection of components and drug products. Specifically, the calibration, airflow and leakage were Other. Also, during the walkthrough of the Microbiological Laboratory, many deviations were observed regarding dust, debris and lack of cleanliness. Specific deviations were observed

- during microbiological testing of Subject Zyrtec Sugar Free Syrup.
- n. **Observation 14:** Laboratory records do not include complete records of the periodic calibration of laboratory instruments, gauges, and recording devices. Specifically, laboratory refrigerators were not calibrated adequately.
  - o. **Observation 15:** Written specifications for laboratory controls do not include a description of the sampling procedures used. Specifically, it does not identify the dilution to use or the microbiological swab used for swabbing equipment after cleaning for Bioburden samples.
  - p. **Observation 16:** Samples taken of in-process materials for determination of conformance to specifications are not representative. Specifically, the raw material sample pulled by the manufacturer is not a representative sample.
  - q. **Observation 17:** Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected. Specifically, there were not separate or defined areas to prevent contamination or mix-ups.
  - r. **Observation 18:** Components are not microscopically examined when appropriate. Specifically, there are no monthly trend reports.
  - s. **Observation 19:** Records are not kept for the maintenance and inspection of equipment.
  - t. **Observation 20:** The persons double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log.

## 2. The December 9, 2010 Report

159. On or about December 9, 2010, the FDA issued another “Form 483” report pertaining to an inspection of the McNeil’s Fort Washington, Pennsylvania facility (“the December 9, 2010 Report”).

160. The December 9, 2010 Report was issued by the local branch of the FDA, located at the United States Customs House, Room 900, 2nd and Chestnut Streets, Philadelphia, Pennsylvania.

161. The December 9, 2010 Report also was authored four local FDA investigators and was issued to Hakan Erdemir, McNeil Consumer Health Care's Vice President of Operations. The December 9, 2010 Report concerned inspections of McNeil which took place between October 27, and December 9, 2010.

162. As detailed in the December 9, 2010 Report, there were seven (7) separate "observations" made by the FDA investigators respecting deficiencies in the manufacturing operations at McNeil. These observations included the following:

- a. **Observation 1:** Procedures describing the handling of written and oral complaints related to drug products are deficiently written.
- b. **Observation 2:** Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and the drug product.
- c. **Observation 3:** There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.
- d. **Observation 4:** Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.
- e. **Observation 5:** Investigations of an unexplained discrepancy and a failure of a batch to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.
- f. **Observation 6:** Written records are not always made of investigations into unexplained discrepancies.
- g. **Observation 7:** The responsibilities and procedures applicable to the quality control unit are not fully followed. (Emphasis added)

#### **G. Congressional Investigations and Hearings**

163. On May 5, 2010, as a direct result of the April 30, 2010 recall of Children's

Tylenol and other Children's Medicines and the Phantom Recall of Motrin, the House Committee on Oversight and Government Reform opened an investigation.

164. The House Committee on Oversight and Government Reform held two hearings in which Johnson & Johnson executives appeared and testified.

165. Then Committee Chairman Edolphus Towns (D. New York) stated that he was "deeply concerned about the recall of popular pediatric medications widely used by infants and children across the country."

166. Then Ranking Minority Member Representative Darrell Issa (R-California) said, "It is a moral outrage for a company specifically marketing its products for children to allow a culture of neglect and irresponsibility to taint the medicines that parents and physicians trust to help children get well."

167. The May 27, 2010 House Committee on Oversight and Government Reform Hearing On May 27, 2010, the Defendant Colleen A. Goggins, Worldwide Chairman of the Johnson & Johnson Consumer Group stated that "[a]cross our organization, we believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers, and all others who use our products and services."

168. Though Ms. Goggins admitted that with respect to the April 30, 2010 recalled products, that J&J and McNeil had "not lived up to that responsibility," she sought to downplay the significance of those recalls by claiming that there were no health risks related to use of the recalled products and thereafter attempted to downplay the particulate contamination by characterizing it as "minute."

169. The September 30, 2010 House Committee on Oversight and Government

Reform Hearing

170. On September 30, 2010, the House Committee held a second hearing, during which Defendant William C. Weldon, Chairman and CEO of J&J admitted that McNeil had secretly bought up defective products without informing regulators and consumers of its actions and that it was clear to him that **“McNeil should have handled things differently.”**

171 In addition, Mr. Weldon apologized for not maintaining “high quality standards” with respect to the recalled children’s and infants’ products, admitted that McNeil and J&J had “let the public down” by not meeting those standards, and accepted **“full accountability for the problems at McNeil.”**

172. Like his underling Defendant Goggins did before him, Defendant Weldon sought to minimize the health risks posed to the general population from the defective products.

173. The following colloquy took place between Representative Elijah Cummings (D-Maryland) and Defendant Weldon:

REP. CUMMINGS: If the product was not good enough, or safe enough to sell, why would it be good enough for consumers to keep it in their homes? In their medicine cabinets?

MR. WELDON: Sir, first of all, I think we had looked at this closely and determined there was **no risk, no safety hazard, no risk to patients who consumed these products**. We thought it was a way to expeditiously get the product out of the market, and I think it was in May that we sent a letter to the customers notifying them of this action and telling them that we wanted to remove the products that were in the facilities.

**H. J&J and McNeil’s Contaminated and Defective Children’s Tylenol Killed Two Year-old River Moore**

174. In 2010, Plaintiff Katy Moore purchased Very Berry Strawberry flavored Children’s Tylenol from Defendant Costco’s store in Union Gap, Washington.

175. J&J and McNeil manufactured the Very Berry Strawberry flavored Children's Tylenol in their contaminated plant located in Fort Washington, Pennsylvania.

176. Very Berry Strawberry flavored Children's Tylenol is numbered NDC 50580-493-04 and has an expiration date of 8/11.

177. The Plaintiffs Katy and Daniel Moore did not know, and would have no way of knowing, about Defendants J&J and McNeil's manufacturing deficiencies, product contamination and quality control issues at their Fort Washington, Pennsylvania facility.

178. On July 22, 2010, River Moore was healthy two-year old who developed a fever.

179. At 11:30 p.m., River awoke with a temperature of 101 degrees.

180. Plaintiff Katy Moore unknowingly administered a defective and contaminated recalled dose of Children's Tylenol.

181. Within 30 minutes of taking the Tylenol, River Moore began spitting up blood.

182. The Children's Tylenol destroyed two year-old River Moore's liver.

183. Plaintiff Katy Moore took her son to Yakima Memorial Hospital.

184. The defective and contaminated Children's Tylenol caused two year old River Moore's liver to fail causing his death on July 23, 2010.

185. As a result of the Defendants' collective misconduct set forth herein, the contaminated and defective Children's Tylenol increased the risk of harm to River Moore and was a substantial contributing factor and factual cause in causing River Moore to suffer:

- a. physical pain and suffering;
- b. depression, anxiety, fear, emotional distress and mental anguish;

- c. loss of enjoyment of life and life's pleasures;
- d. loss of earnings;
- e. medical expenses;
- f. all injuries and damages as set forth in River Moore's medical records;  
and
- g. such other injuries, damages and losses as described more fully herein.

**COUNT I – STRICT LIABILITY**

**Restatement of Torts (Second) § 402A**

**Plaintiffs v. Defendants Johnson & Johnson, McNeil-PPC, Inc.,  
McNeil Consumer Healthcare, McNeil Consumer & Specialty Pharmaceuticals  
Costco Wholesale Corporation, William C. Weldon and Colleen Goggins**

186. Plaintiffs incorporate each and every allegation above as if set forth at length herein.

187. Defendants Johnson & Johnson, McNeil-PPC, Inc., McNeil Consumer Healthcare, McNeil Consumer & Specialty Pharmaceuticals, Costco Wholesale Corporation and William C. Weldon and Colleen Goggins (the "Manufacturing and Distributing Defendants") are strictly liable for the injuries and damages suffered by decedent River Moore as a consequence of the defect in the drug, Children's Tylenol, pursuant to the provisions of the Restatement Second of Torts §402A and the applicable law.

188. The Children's Tylenol was defectively designed, manufactured, tested, promoted, advertised, labeled, marketed, distributed, and/or sold by the Manufacturing and Distributing Defendants so as to render it unreasonably dangerous to plaintiff and others similarly situated.

189. Manufacturing and Distributing Defendants placed into the stream of commerce defective, contaminated and impure Children's Tylenol which made it dangerous to the health